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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,640	02/07/2001	Babak Nemati		4426

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EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/777,640	NEMATİ, BABAK	
	Examiner	Art Unit	
	Michael J Hayes	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 71-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pore forming portion, delivery portion, and optical portion as recited in claims 71, 78, and 86, confocal microscope as part of the apparatus and spectral information device as part of the apparatus as recited in claim 73, laser irradiation portion as recited in claim 74, driver portion that drives via iontophoresis, electroporation, acoustic pressure, or application of enhancer, agent, or solvent, as recited in claim 79, and an optical portion configured to acquire an analyte signal as recite in claim 84 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74 and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not described how to combine an optical portion with

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iontophoresis, electroporation, acoustic pressure application, or a laser irradiation pore forming portion to enable its use or manufacture.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78 and 80-90 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINEZ (U. S. Patent No. 4,222,375). Martinez discloses an apparatus capable of enhancing the optical transparency of biological tissue comprising means for bypassing the surface barrier (needle 58), means for delivering clarifying agent (syringe), means for delivery of light (fiber optic cable 38 coaxial with the needle). The various uses recited in the claims are readable on the prior art because the prior art is capable of performing these functions and supplying light for these functions. See figs. 3, 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 71-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN et al. (US Patent No. 6,275,726) in view of MARTINEZ. Chan discloses means for bypassing the surface permeability barrier of tissue, means for delivering a clarifying agent, means of light delivery for diagnostic and therapeutic applications, and a device to

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provide spectral information. When using the jet injector embodiment disclosed by Chan the device is non-invasive and is capable of remaining proximal to the barrier (1:50-65; 2:24-32; 3:51-67; 4:1-12; 7:25-65; 8:37-40). Chan does not disclose the fluid delivery device and light delivery device in one apparatus. Martinez teaches incorporating a fluid delivery device and light delivery device in one apparatus (figs. 3, 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Martinez in the apparatus of Chan in order to accomplish the precise application of light during surgical operations (Martinez 1:15-17).

Claim 79 is rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINEZ as applied to claim 78 above, and further in view of EDWARDS (U. S. Patent No. 5,833,647). Martinez discloses the claimed invention except for bypassing means including iontophoresis system, electric pulse generator, or acoustic generator. Edwards teaches using these methods which inherently require the appropriate systems and generators to drive molecules. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Edwards in the invention of Martinez in order to deliver an agent across the skin barrier.

Response to Arguments

Applicant has canceled claims 1-70 and has submitted new claims 71-90.

Applicant has made some arguments with respect to the new claims and the prior art of record. The examiner responds below to these arguments as appropriate.

Applicant argues that Martinez does not show light passing through the barrier to an area below. The examiner's position is that this limitation is directed to the use of the

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device and if the prior art is capable of this use then the claims read on the prior art.

Martinez is capable of this use. Merely using an old device in a new manner does not carry patentable weight.

Applicant argues that Chan teaches chemical abrasion and mechanical debridement. Applicant neglects to state that Chan teaches delivery by needle injection and jet injection. Chan is capable of performing the functional limitations in the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EPPSTEIN (U. S. Patent No. 6,527,716) shows various devices for bypassing a surface permeability layer to deliver agents to covered biological tissues.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
4 June 2004



MICHAEL J. HAYES
PRIMARY EXAMINER